APPENDIX 1

ROBUST SUMMARY OF GENETIC TOXICITY AND REPEATED DOSE MAMMALIAN TOXICITY TESTING COMPLETED ON ISODECYL DIPHENYL PHOSPHATE

GENETIC TOXICITY

Test material:	Isodecyl diphenyl phosphate (Lot QH-28641)
Type:	*In vitro* mammalian cell mutation
Cell type:	Fischer mouse lymphoma L5178Y derived
Metabolic activation:	Male F-344 rat liver 9000 x G supernatant, Arochlor 1254 induced Assay run with and without activation
Solubility, cytotoxicity determination:	Solubility and toxicity were determined with 4-hour incubation followed by 24-hr expression times in at least 4 dose levels bracketing the concentrations used in definitive testing.
Number of concentrations evaluated:	Positive control, negative control, vehicle control, 5 test concentrations with and without activation
Results:	No evidence for mutagenic activity in the presence or absence of exogenous metabolic activation. Cytotoxicity was produced in the highest concentrations of isodecyl diphenyl phosphate tested with activation.
Reliability:	Reliable
GLP:	Work conducted prior to inception of GLP regulations
Reference:	Litton Bionetics Inc. report 20989, "Mutagenicity Evaluation of S-148 BO-78-85 in the Mouse Lymphoma Forwatrd Mutation Assay" Kensington, MD., August, 1978. D. Matheson, Ph.D., Author.

REPEAT DOSE MAMMALIAN TOXICITY

Oral Toxicity

Test material:	Isodecyl diphenyl phosphate (Lot DC 5A83) 98.4% purity)
Type:	Repeat-dose oral – dietary admixture
Species:	Rat
Strain:	Sprague-Dawley
Sex:	Female and male
Number of animals per dose level:	30, weight range: males 106-143 at study initiation females: 104-133 at study imitiation
Number of dose levels:	Three plus untreated control 140 ppm in diet 1400 ppm in diet 7000 ppm in diet
Administration:	Daily for 90 days
Observations:	Clinical observation Food consumption Body weight Mortality Clinical pathology at mid-study and termination hematology serum chemistry urinalysis Gross and microscopic pathology Organ weights Electron microscopy Analysis of test material and dietary mixtures
Results:	Survival was unaffected by treatment. Dose-related male and female reduced body weight gain (slightly >10% in high dose groups) and reduced food consumption. Lymphocytopenia, decreased red cell indices, increased gamma-GT, as well as other indicators of liver cytotoxicity and/or function, hepatocellular hypertrophy and hyperplasia. No treatment-related changes in any organ or tissue

except liver.

Reliability: Reliable

GLP: Work conducted prior to inception of GLP regulations

Reference: Monsanto Company Environmental Health Laboratory Report number 820160, "Subchronic Study of Santicizer 148 Plasticizer Administered in the Diet to Albino Rats" St. Louis, MO., February, 1986, M. W. Naylor, Study Director